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(71) Applicants: BRUN, Heidi, M. [US/IL]; 7 Halris Street, 99512 Bet Shemesh (IL). MEDINOL LTD. [IL/IL]; Kiryat Atidim, P.O. Box 58165, 61581 Tel Aviv (IL).

(72) Inventors: ISRAEL, Henry, M.; 39 Ben Zakai Street, Bnei Brak (IL). PINCHASIK, Gregory; 23 Golomb Street, Ramat Hasharon (IL).

(74) Agents: GUNNISION, Forrest, E. et al.; Skjerven, Morrill, MacPherson, Franklin & Friel, Suite 700, 25 Metro Drive, San Jose, CA 95110 (US).

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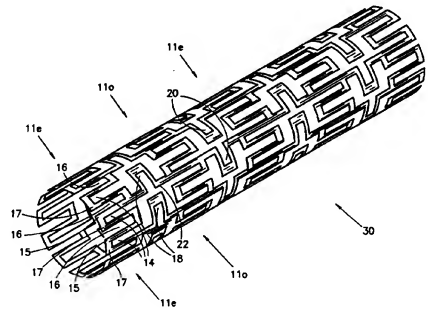
(54) Title: A FLEXIBLE EXPANDABLE STENT



(57) Abstract

There is disclosed a stent (30) for implanting in the body. The stent (30) is formed of a tube having a patterned shape which has first and second meander patterns (11, 12) having axes extending in first and second directions. The first meander patterns can be formed into even and odd first meander patterns. The even and odd first meander patterns are 180 degrees out of phase with each other, and the odd patterns occur between every two even patterns. The second meander patterns are intertwined with the first meander patterns. The first and second directions can be orthogonal to each other. The second meander patterns can also be formed of even and odd patterns.

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A FLEXIBLE EXPANDABLE STENT

FIELD OF THE INVENTION

The present invention relates generally to stents for implanting into a living body.

BACKGROUND OF THE INVENTION

Various stents are known in the art wherein, for the present application, the term "stent" indicates a device, made of body-compatible material, which is utilized to widen a blood vessel, or other orifice in the body, and to maintain the resultant size of the lumen. Typically, the stent is delivered to the desired location in the body with an inflatable balloon and, when the balloon is inflated, the stent expands, thereby widening the orifice. Other mechanical devices which cause expansion of the stent are also utilized.

Exemplary patents in the field of stents formed of wire are: U.S. 5,019,090 to Pinchuk, U.S. 5,161,547 to Tower, U.S. 4,950,227 to Savin, et al., U.S. 5,314,472 to Fontaine, U.S. 4,886,062 and U.S. 4,969,458 to Wiktor and U.S. 4,856,516 to Hillstead. Stents formed of cut stock metal are described in: U.S. 4,733,665 to Palmaz, U.S. 4,762,128 to Rosenbluth, U.S. 5,102,417 to Palmaz and Schatz, U.S. 5,195,984 to Schatz and WO 91 FR013820 to Meadox.

The stents described in U.S. 5,102,417 to Palmaz and Schatz have expandable tubular grafts connected together with a flexible connector. The grafts are formed of a plurality of slots disposed parallel to the longitudinal axis of the tube. The flexible connectors are helical connectors. Since the tubular grafts are relatively rigid, the flexible connectors are needed so that the stents can bend when being fed through a curved blood vessel. When the stents of U.S. 5,102,417

expand, the grafts expand radially and, consequently, shrink longitudinally. However, at the same time, the helical connectors twist. The twisting motion is most probably harmful to the blood vessel.

U.S. 5,195,984 to Schatz describes a similar stent but with one straight connector, parallel to the longitudinal axis of the tubular grafts, between tubular grafts. The straight member removes the twisting motion; however, it is not a very strong connector.

SUMMARY OF THE PRESENT INVENTION

It is therefore an object of the present invention to provide a flexible stent which minimally shrinks, in the longitudinal direction, during expansion.

The stent of the present invention is formed of a tube having a patterned shape which has first and second meander patterns having axes extending in first and second directions wherein the second meander patterns are intertwined with the first meander patterns. The first and second directions can be orthogonal to each other.

In accordance with one embodiment of the present invention, the first meander patterns are formed into even and odd first meander patterns. The even and odd first meander patterns are 180° out of phase with each other and the odd patterns occur between every two even patterns. The second meander patterns can also be formed of even and odd patterns.

Additionally, in accordance with a preferred embodiment of the present invention, the second meander patterns have two loops per period and the even and odd first meander patterns are connected on first and second sides, respectively, of each loop of the second meander patterns.

Alternatively or in addition, the second meander

patterns are formed of even and odd second meander patterns. In this embodiment, the even and odd first meander patterns have loops and the even and odd second meander patterns are connected to the even and odd first meander patterns so as to leave one full loop between each pair of even and odd second meander patterns.

Moreover, in accordance with a preferred embodiment of the present invention, the first and second meander patterns are formed from flat metal. Alternatively, they can be cut from wire. Further, they can be imbedded or covered with any body-compatible material.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is an illustration of a patterned stent, constructed and operative in accordance with a first preferred embodiment of the present invention;

Fig. 2 is an illustration of the pattern of the stent of Fig. 1;

Fig. 3 is an illustration of the stent of Fig. 1 in a bent position;

Fig. 4 is an illustration of the stent of Fig. 1 in an expanded format;

Figs. 5A and 5B are illustrations of the changes in the patterns of the stent of Fig. 1 due to expansion;

Fig. 6 is a schematic illustration of a second embodiment of the pattern for a stent;

Fig. 7 is an illustration of a third embodiment of the pattern for the stent; and

Fig. 8 is an illustration of the pattern of Fig. 7 in an expanded format.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1 - 4 which illustrate a first embodiment of a stent, constructed and operative in accordance with the principles of the present invention. Fig. 1 illustrates the stent in its non-expanded form, Fig. 2 illustrates the pattern of the stent, Fig. 3 illustrates it in a partially bent position and Fig. 4 illustrates it in an expanded form.

The stent of the present invention is a tube whose sides are formed into a plurality of each of two orthogonal meander patterns which patterns are intertwined with each other. The term "meander pattern" is taken herein to describe a periodic pattern about a center line and "orthogonal meander patterns" are patterns whose center lines are orthogonal to each other.

In the stent of Figs. 1 - 4, the two meander patterns are labeled 11 and 12 and they are most easily seen in Fig. 2. Meander pattern 11 is a vertical sinusoid having a vertical center line 9. Meander pattern 11 has two loops 14 and 16 per period wherein loops 14 open to the right while loops 16 open to the left. Loops 14 and 16 share common members 15 and 17, where member 15 connects from one loop 14 to its following loop 16 and member 15 connects from one loop 16 to its following loop 14.

Meander pattern 12 is an horizontal pattern having an horizontal center line 13. Meander pattern 12 also has loops, labeled 18 and 20, but between loops of a period is an extended straight section labeled 22. Loops 18 open downwards and loops 20 open upwards. Vertical meander pattern 11 is provided in odd and even (o and e) versions which are 180° out of phase with

each other. Thus, each left opening loop 16 of meander pattern 11o faces a right opening loop 14 of meander pattern 11e and a right opening loop 14 of meander pattern 11o faces a left opening loop 16 of meander pattern 11e.

Horizontal meander pattern 12 is also provided in odd and even forms. The straight sections 22 of horizontal meander pattern 12e intersect with every third common member 17 of vertical meander pattern 11e. The straight sections 22 of horizontal meander pattern 120 intersect with every third common member 15 of vertical meander pattern 11e. beginning with the common member 15 two after an intersected common member 17. The result is a full loop 14 between meander patterns 12e and 120 and a full loop 16 between meander patterns 12o and 12e.

Returning to Fig. 1, the pattern of Fig. 2 is formed into a tube 30 of an easily deformable material, such as a metal. Due to the two meander patterns, the stent of Fig. 1, when attached over a catheter balloon, is flexible and can therefore be easily dragged through curved blood vessels. An example of the way in which the stent of Fig. 1 bends is illustrated in Fig. 3.

In Fig. 3, the stent begins to bend at the point marked A in the direction marked by arrow 40. As the stent begins to curve, the section marked I becomes the inside of the curve while the section marked O becomes the outside of the curve. The inside of the curve I is shortened vis-a-vis the outside of the curve O.

During bending, the loops 14 - 20 to the right of the point A change shape in order to compensate for the differences in length between the inside and outside curves. For example, loops 18i and 20i near the inside of the curve are closer together than loops 180 and 200 on the outside of the curve, which expand. Loops 14i and 16i near the inside I are compressed while the

loops 140 and 160 closer to the outside O of the curve are expanded.

As can be seen, both meander patterns 11 and 12 are involved in the bending. Although not shown, it will be appreciated that the stent of Figs. 1 - 4 can bend in any direction and in more than one direction at any time.

Fig. 4 illustrates the stent of Fig. 1 in its expanded form. When the stent expands, both meander patterns 11 and 12 expand (i.e. all loops 14 - 20 open up). As can be seen, the expanded stent has two types of enclosed spaces, a large space 42 between meander patterns 120 and 12e and a small space 44 between meander patterns 12e and 12o. As can also be seen, each large space 42 has two loops 14 on its left side and two loops 16 on its right side. The large spaces between vertical meander patterns 11e and 11o, which are labeled 42a, have loops 18 at their tops and bottoms while the large spaces between vertical meander patterns 11o and 11e, which are labeled 42b, have loops 20 at their tops and bottoms. Similarly for small spaces 44a and 44b.

It is noted that, due to the orthogonal meander patterns 11 and 12, the stent of Fig. 1 does not significantly shrink during expansion. This is illustrated in detail in Figs. 5A and 5B to which reference is now made. Fig. 5A illustrates the movement, during expansion, of one vertical meander pattern 11 and Fig. 5B illustrates the movement, during expansion, of one horizontal meander pattern 12. The original patterns are shown with solid lines and the expanded patterns are shown with dashed lines.

The vertical meander pattern 11 of Fig. 5A expands by widening its loops 14 and 16. As a result, the vertical meander pattern 11 grows vertically by an amount $2*h_1$, per loop. However, it also shrinks

horizontally, by an amount $2*d_1$. Similarly, the horizontal meander pattern 12 of Fig. 5B expands by widening its loops 18 and 20. As a result, the horizontal meander pattern 12 grows horizontally by an amount $2*d_2$ per loop. However, it also shrinks vertically, by an amount h_2. Thus, the vertical growth of the vertical meander pattern 11 compensates, at least partially, for the vertical shrinkage of the horizontal meander pattern 12, and vice versa. It is noted that the end portions of any stent are only partially compensated and therefore, may shrink somewhat.

It will be appreciated that the two orthogonal meander patterns 11 and 12 and the compensation they provide to each other provides flexibility to the unexpanded stent of Fig. 1. However, when the stent is expanded, the changes in each of loops 14 and 16 provide rigidity to the resultant stent and thus, enable the stent to maintain a blood vessel at a desired inner diameter.

The stent of the present invention can be manufactured from flat metal which is etched into the pattern of Fig. 2. The etched metal is then bent to form the tube 30. Alternatively, the pattern of Fig. 2 can be manufactured from welded or twisted wire.

It will be appreciated that the stent of the present invention can be made from metal and/or wire. Additionally, it can be plated with a protective material, embedded with a medicine, and/or covered with a material which can fill in the spaces 42 and 44.

It will be appreciated that the present invention encompasses all stents manufactured with a pattern formed of two meander patterns, orthogonal or otherwise. Another exemplary pattern, also with orthogonal meander patterns, is provided herein wherein Fig. 6 is a schematic version and Fig. 7 is a more

rounded version. Fig. 8 shows the pattern of Fig. 7 in an expanded format. The pattern of Figs. 6 and 7 is similar to that shown in Fig. 2 except that it has more horizontal meander patterns 12 and they are of one kind, rather than being even and odd as in Fig. 2.

As can be seen in both Figs. 6 and 7, there are two types of vertical meander patterns 11e and 11o which are 180° out of phase with each other. The horizontal meander patterns 12 connect with every line 15 of vertical meander pattern 11e.

Fig. 8 illustrates the pattern of Fig. 7 in an expanded format. Since there are no even and odd horizontal meander patterns, in the expanded format of Fig. 8, there are no large and small spaces. Instead, all spaces are of the same size.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the claims which follow:

CLAIMS

1. A stent formed of a tube having a patterned shape, the patterned shape comprising:

a. even first meander patterns having axes extending in a first direction;

b. odd first meander patterns, also having axes extending in said first direction, wherein said odd first meander patterns are 180° out of phase with said even first meander patterns and occur between every two even first meander patterns;

c. second meander patterns having axes extending in a second direction different than said first direction, wherein said second meander patterns are intertwined with said even and odd first meander patterns to form a generally uniform distributed structure.

2. A stent according to claim 1 and wherein said even first meander patterns and said odd first meander patterns are periodic about axes extending in said first direction and wherein said second meander patterns are periodic about axes extending in said second direction.

3. A stent according to either of claims 1 or 2 and wherein said second meander patterns have two loops per period and wherein said even and odd first meander patterns are connected on first and second sides, respectively, of each loop.

4. A stent according to any of the previous claims and wherein said second meander patterns are formed of even and odd second meander patterns.

5. A stent according to claim 4 and wherein said

even and odd first meander patterns have loops and wherein said even and odd second meander patterns are connected to said even and odd first meander patterns so as to leave one full loop between each pair of even and odd second meander patterns.

6. A stent formed of a tube having a patterned shape, the patterned shape comprising:

a. first meander patterns having axes extending in a first direction;

b. second meander patterns having axes extending in a second direction, different than said first direction, wherein said second meander patterns are intertwined with said even and odd first meander patterns to form a generally uniform distributed structure.

7. A stent according to claim 6 and wherein said first meander patterns are periodic about axes extending in said first direction and wherein said second meander patterns are periodic about axes extending in said second direction.

8. A stent according to any of claims 1 - 7 and wherein said first and second directions are orthogonal.

9. A stent according to any of claims 1 - 7 and wherein said first and second directions are not orthogonal.

10. A stent according to any of claims 1 - 9 and wherein said first and second meander patterns are formed from wire.

11. A stent according to any of claims 1 - 9 and

wherein said first and second meander patterns are cut from flat metal.

12. A stent according to any of the previous claims and wherein said stent is finished in one of the following ways: plating with a protective material, embedding with medicine, and covered with a material.

13. A stent, comprising:

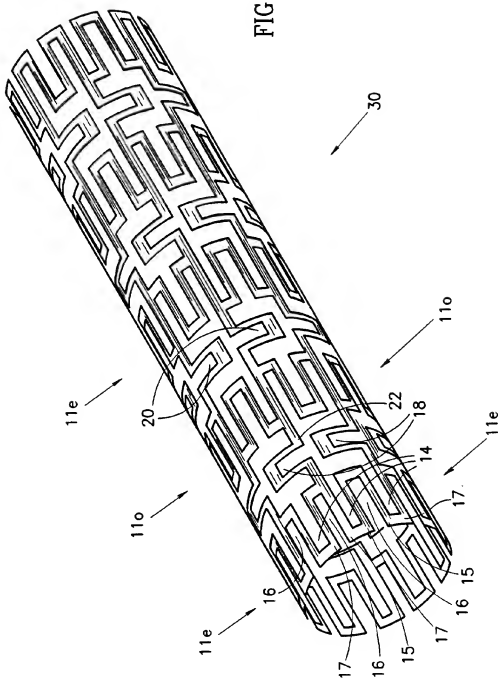
a. at least odd and even alternating serpentine sections, each having first areas of inflection, wherein said odd serpentine section is out of phase from said even serpentine section such that first areas of inflection on said odd serpentine section are adjacent first areas of inflection on said even serpentine section; and

b. at least one flexible connector, comprising a plurality of flexible links connecting adjacent first areas of inflection of adjacent even and odd serpentine sections, wherein each flexible link has at least two portions connected by at least one second area of inflection, and wherein said first and second areas of inflection define first and second angles whose bisecting lines are at angles one to another.

14. A stent comprising a mesh of adjacent, connected cells, each cell comprising:

an even number of fixed length, alternating, first and second loops, connected together in a closed cell, each loop having at least two portions with an area of inflection there between, said first and second loops defining first and second angles whose bisecting lines are at angles one to another.

FIG.1



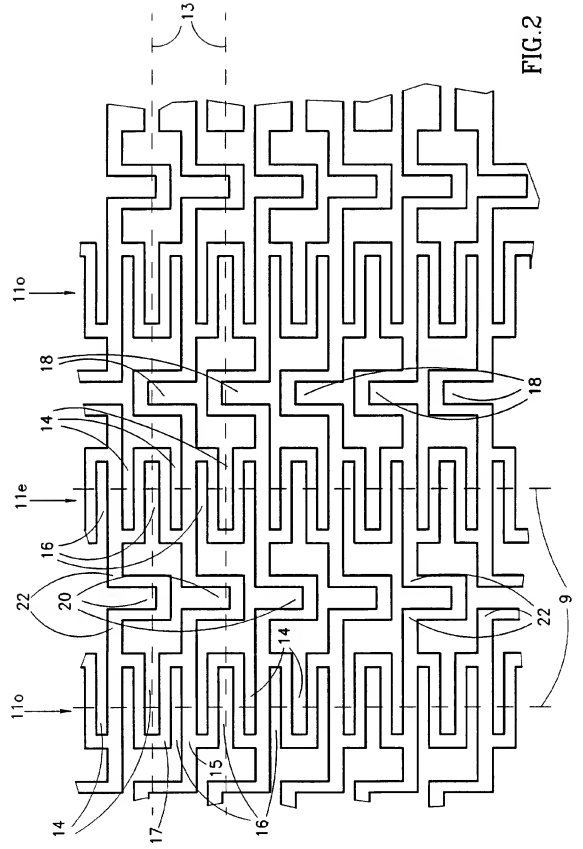


FIG.2

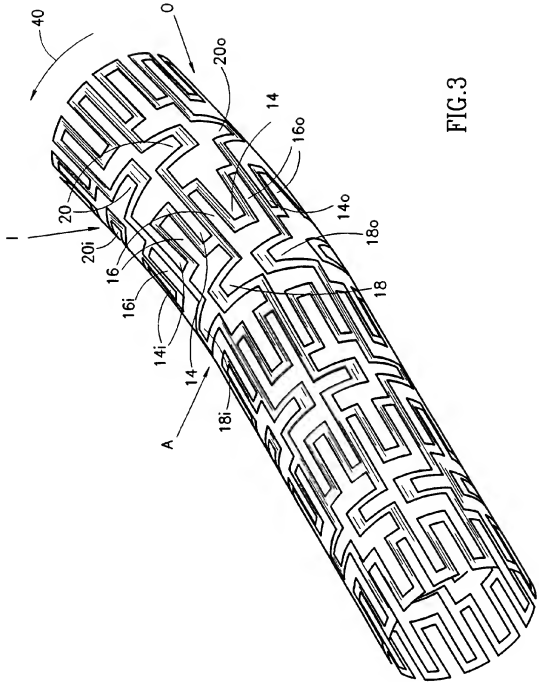


FIG.3

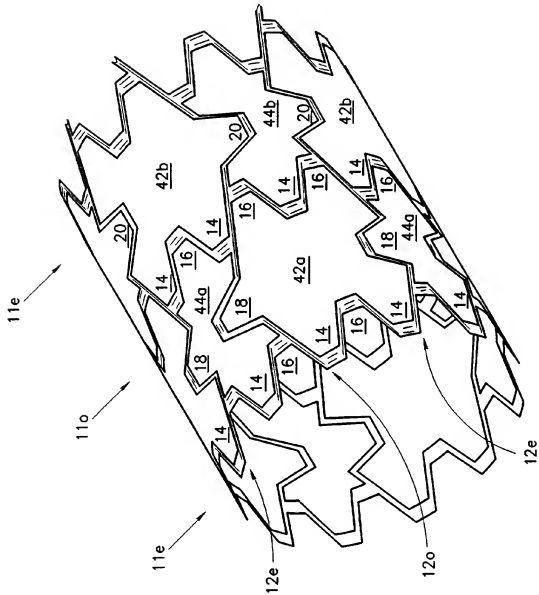


FIG.4

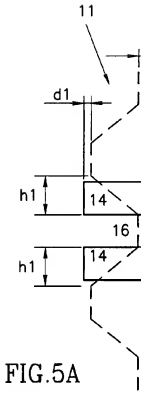


FIG.5A

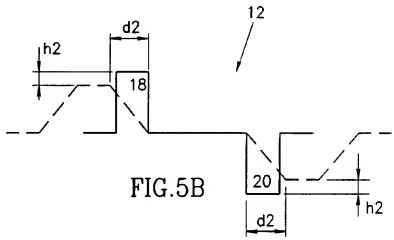


FIG.5B

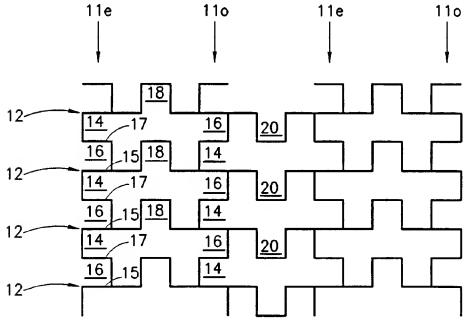


FIG.6

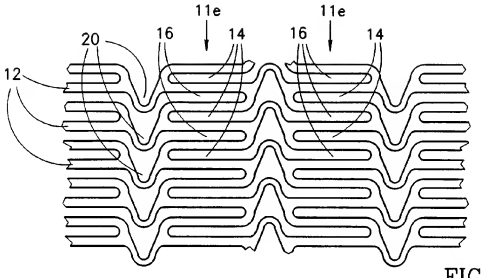


FIG.7

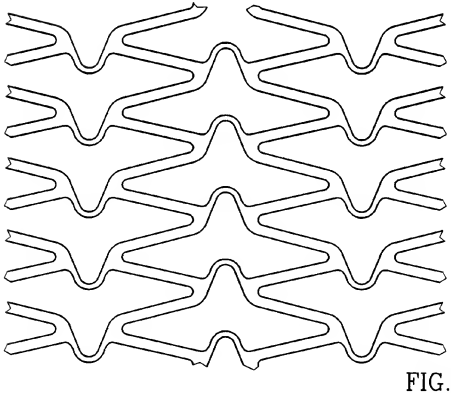


FIG.8

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

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B. FIELDS SEARCHED

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U.S. : 606/108, 191, 194, 198, 200; 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, E	US, A, 5,449,373 (PINCHASIK ET AL.) 12 September 1995, see entire document.	1-14
A	EP, A, 0 606 165 (MIKSZA) 13 July 1994, see entire document.	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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(71) Applicants:
- **CORDIS EUROPA N.V.**
  NL-9301 LJ Roden (NL)
- **Sheiban, Imad**
  I-37126 Verona (IT)

(72) Inventors:
- **Sheiban, Imad**
  I-37126 Verona (IT)
- **Nap, Cornelis Philipus**
  NL-9345 AC Zevenhuizen (NL)

(74) Representative: **'t Jong, Bastiaan Jacobus**
Arnold & Siedsma,
Advocaten en Octrooigemachtigden,
Sweelinckplein 1
NL-2517 GK Den Haag (NL)

(54) Catheter for stent implantation

(57) The invention relates to a catheter comprising a tube-like basic body with a proximal and a distal end, at least one balloon member arranged close to the distal end. This balloon member is connected via a lumen in the basic body to a connecting member at the proximal end. Close to either end of the balloon member a bulge has been arranged to the basic body and wherein a compressed stent has been arranged around the balloon member and in between the bulges. The bulges have been arranged inside the balloon-shaped member.

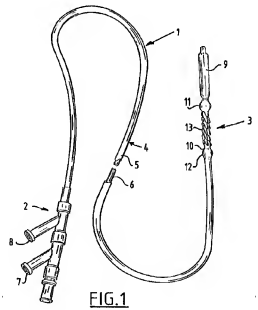

FIG.1

EP 0 707 837 A1

Description

The invention relates to a catheter used for the implantion of a stent in a patient. A stent is a tubular element, usually made of wire mesh, which can be expanded in cross-sectional direction. Such an element is for instance introduced into a blood vessel of a patient, of which the wall has been impaired to such a degree, that there is a risk of collapse of the blood vessel concerned. The stent is introduced in a compressed state and expanded when situated in the required position, thus supporting the wall of the blood vessel. Expansion is usually achieved by means of the balloon of a balloon catheter. Stents and catheters employed for the introduction thereof are known as such, and are for instance described in the American patent specification 5 226 889.

The object of this invention is to provide an improvement of known catheters used for the purpose of stent-implantation.

This aim has been achieved with the catheter according to the invention as characterised in claim 1. By employing the bulges in between which the stent is retained, the stent can be fixed securely at the site of the balloon used for expanding the stent. The stent cannot slide off the balloon. Because of this proper fixation of the stent, the use of a so-called sheath is superfluous, thus simplifying the treatment to be carried out using the catheter according to the invention. The bulges can consequently be arranged relatively close to each other, without limiting the expansion possibilities of the balloon. Consequently the stent can be fixed properly in the centre of the balloon. In the non-expanded state, the balloon fits closely over the bulges, so that the surface of the catheter in a longitudinal direction over the bulges is smooth.

For a good fixation of the stent it is sufficient if, in relation to the inside diameter of the compressed stent, the bulges are such that the stent cannot slide over these bulges. Preferably however the measure as characterised in claim 2 is employed. Consequently the stent is, as it were, situated in a depression or "bed" defined by the bulges, as a result of which the stent does not interfere with the introduction of the catheter.

A suitable embodiment is characterised in claim 3. The measure as set out in claim 4 is preferably employed. Both rings and therefore the position of the stent retained in between them, is in this way properly observable so that the stent can be manoeuvred carefully into the correct position.

Preferably the measure as set out in claim 5 is employed. The relatively distal balloon member can be used for dilatation of that section of the blood vessel where the stent is to be implanted, even when there is a severe stenosis. After dilatation of the blood vessel with the relatively distal balloon, the catheter is advanced a little further, thus positioning the stent in the dilated section of the blood vessel. Next the balloon around which the stent has been arranged can be expanded, as a result of which the stent will expand and provide the wall of the vessel with the required support. Thus, using one single catheter, and in one session, the vessel can be dilated and the stent implanted.

A suitable embodiment is characterised in claim 6.

The invention will be explained in greater detail in the following description with reference to the attached drawings.

Figure 1 shows a partly broken away, perspective view of a catheter according to the invention.

Figure 2 shows a partly cut away view of the distal end of the catheter of figure 1.

Figure 3 shows the catheter section shown in figure 1 during a first step of the treatment for which it is to be used.

Figure 4 shows a view corresponding to figure 3 of a second step of the treatment.

Figure 5 shows a view corresponding to figure 3 and 4 of a third step of the treatment.

Figure 6 shows schematically the treated blood vessel with the stent in position, following the removal of the catheter.

Figure 7 shows a partly broken away, perspective view of a catheter according to another embodiment of the invention.

The catheter 1 shown in figure 1 comprises a tube-like basic body 4 which in this case is made up of an outer tube-like element 5 and an inner tube-like element 6 received inside a lumen thereof. The inner tub-like element 6 has two lumens 16, 17. With the embodiment shown, two balloon members 9, 10 have been arranged at the distal end 3 of the catheter 1. At the proximal end 2 two connecting members 7, 8 have been arranged which are connected to the balloon member 9 and the balloon member 10 respectively. By supplying medium under pressure via the connectors 7 or 8, the balloon members 9 or 10 can be expanded. The connection between the connecting member 7 and the balloon member 9 runs via lumen 17 of the inner tube-like element 6 and the connection between the connecting member 8 and the balloon member 10 runs via the interspace 20 in between the inner tube-like element 6 and the outer tube-like element 5. Lumen 16 is intended for receiving a guide wire.

On both sides of the balloon member 10, the catheter 1 has been provided with bulges 11, 12. A compressed stent 13 has been arranged around the balloon 10 in between those bulges 11 and 12. The stent 13 is enclosed by the bulges 11 and 12 in the axial direction of the catheter 1, so that it cannot slide off the balloon 10.

As can be seen in figure 2 et seq. in particular, the bulges 11 and 12 in this embodiment are formed by respective rings 14 and 15 which have been received inside the balloon 10. The ring 14 has been arranged around the continuous inner tube-like element 6 and the ring 15 has been arranged around the end of the outer

tube-like element 5. As the rings 14, 15 have been arranged inside the balloon 10 they do not interfere with the unfolding of the balloon 10, and the balloon forms a smooth "skin" over the rings 14, 15, which is favourable when introducing the catheter.

The distal end 3 of the catheter 1 is introduced into a blood vessel 18 of a patient inside of which the stent 13 is to be implanted. The embodiment of the catheter according to the invention shown here is provided with the balloon 9 for dilating a narrowed blood vessel 18, in addition to the balloon 10 designed for expanding the stent 13. By employing the two balloons 9, 10, dilating the vessel and implanting the stent can be achieved using one and the same catheter 1, without it being necessary to change catheters.

With the treatment the catheter 1 is first introduced into the blood vessel 18 to such a degree that the first balloon 9 is positioned at the stenosed section which is to be dilated. Subsequently a medium under pressure is supplied via the connecting member 7 through the lumen 17 of the inner tube-like element 6. Via the opening 21 in the wall of the inner tube-like member this medium under pressure flows into the balloon 9 as a result of which it will expand. Consequently the blood vessel 18 will be dilated (fig. 3).

Next the pressure inside the balloon 9 will be reduced, as a result of which it will resume its original shape. The catheter is advanced further into the vessel so that the balloon 10 will be situated at the dilated section of the vessel. By supplying medium under pressure to balloon 10 via connector 8 and the interspace between the tube-like elements 5, 6, which interspace is connected with the inside of the balloon 10 at the end of the outer tube-like element 5 as a ring-shaped opening 20, this balloon 10, and hence the stent 13, will be expanded. This situation has been illustrated in figure 4.

Subsequently one allows the pressure in the balloon 10 to fall, as a result of which the balloon 10 will resume its original shape with small diameter as shown in figure 5. The catheter can now be withdrawn, whereby as is shown in figure 6, the stent 13 remains behind in the blood vessel 18, in order to support the wall thereof.

The catheter and the accompanying stent shown in the figures only represent examples of embodiments. Other embodiments of stents known as such, can be used in conjunction with the catheter according to the invention. Because of the good axial fixation of the stent, the latter will remain positioned in a reliable manner at the site of the balloon used for the purpose of expansion, so that it is not necessary to use a guiding catheter or a sheath.

The catheter according to the invention may comprise any number of balloon-shaped members, of which at least one comprises bulges on either side to retain a stent.

In the embodiment shown, the rings 14 and 15 have been made of material which is clearly visible when subjected to X-rays, so that the position of these rings 14, 15 and consequently the position of the stent, placed in between these bulges, can be rendered clearly visible in a catheterization laboratory.

The catheter 21 shown in figure 7 corresponds for the major part with the catheter 1 of figure 1. This catheter 21 thus comprises a tube-like basic body 22 with a distal end 25 and a proximal end 26. At the distal end 25 two balloons 27, 28 have been arranged. The balloon 27 is for dilating a narrowed section of a blood vessel. Around the balloon 28, a stent 29 has been arranged in compressed state. This stent 29 can be expanded, as described before, by means of the balloon 28 and thus be implanted in the section of the vessel dilated beforehand by means of the balloon 27.

With the embodiment shown, the basic body 22 is made up of an outer tube-like element 23 and an inner tube-like element 24. A lumen inside the inner tube-like element 24 has at the proximal end of the catheter 21 been connected to a connection 34, and at the distal end to the inside of the balloon 27 in order to convey medium under pressure from the connection 34 to the balloon 27 in order to expand the latter. In between the inner tube-like element 24 and the outer tube-like element 23, a in cross-section circular lumen is formed which, at the proximal end 26 of the catheter, is connected to the connection 30 and at the distal end 25 to the inside of the balloon 28 in order to be able to expand the latter in a similar manner.

For introducing the catheter into a patient a guide wire 31 is employed in the usual manner. For the purpose of receiving this guide wire 31 a lumen 36 has been formed in the catheter 21 which extends from an end hole 32 to a wall hole 33 in the catheter. This wall hole has been arranged in the wall of the basic body 22 at a position in between the distal and the proximal end.

With the preferred embodiment shown in figure 7, the wall hole has been arranged close to the relatively proximal active element of the catheter 21, the balloon 28. The lumen 36 for receiving the guide wire 31 only extends therefore through the end-section of the catheter 21.

Claims

1. Catheter comprising a tube-like basic body with a proximal and a distal end, at least one balloon member arranged close to the distal end which is connected via a lumen in the basic body to a connecting member at the proximal end, wherein close to either end of the balloon member a bulge has been arranged to the basic body and wherein a compressed stent has been arranged around the balloon member and in between the bulges, and wherein the bulges have been arranged inside the balloon-shaped member.

2. Catheter as claimed in claim 1, wherein the outside diameter of the compressed stent is smaller than the outside diameter of the catheter at the site of the bulges.

3. Catheter as claimed in one of the previous claims, wherein the bulges are formed by rings arranged around the basic body.

4. Catheter as claimed in claim 3, wherein each ring has been made of material visible when subjected to X-rays and/or when used in conjunction with an NMR device.

5. Catheter as claimed in one of the previous claims, comprising two successive balloon members, wherein the bulges and the stent are arranged at the site of the relatively proximal balloon member.

6. Catheter as claimed in claim 5, wherein the basic body comprises an outer tube-like element with a lumen inside of which an inner tube-like element has been received, a lumen of the inner tube-like element has been connected with the relatively distal balloon member and the interspace between the inner tube-like member and the outer tube-like member is connected with the comparatively proximal balloon-shaped member.

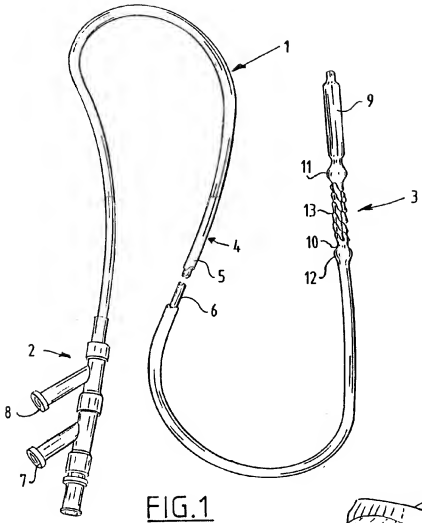

FIG.1

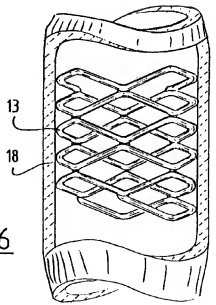

FIG.6

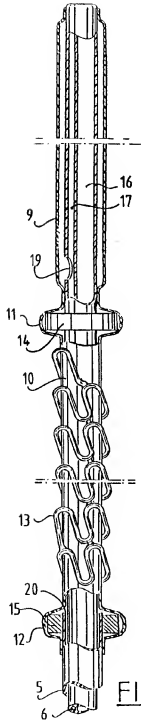

FIG.2

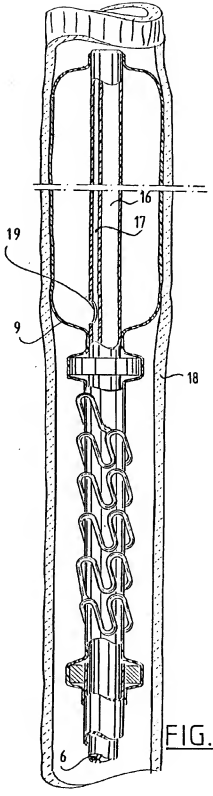

FIG.3

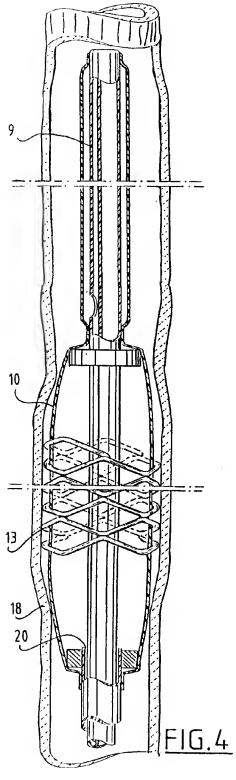

FIG.4

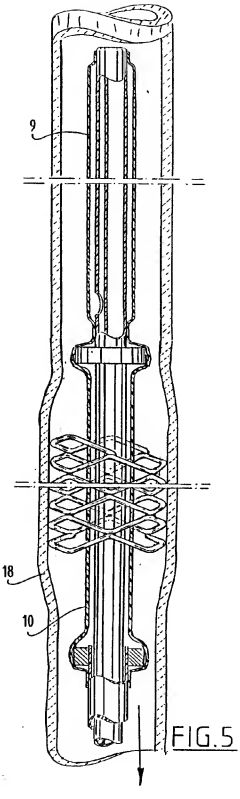

FIG.5

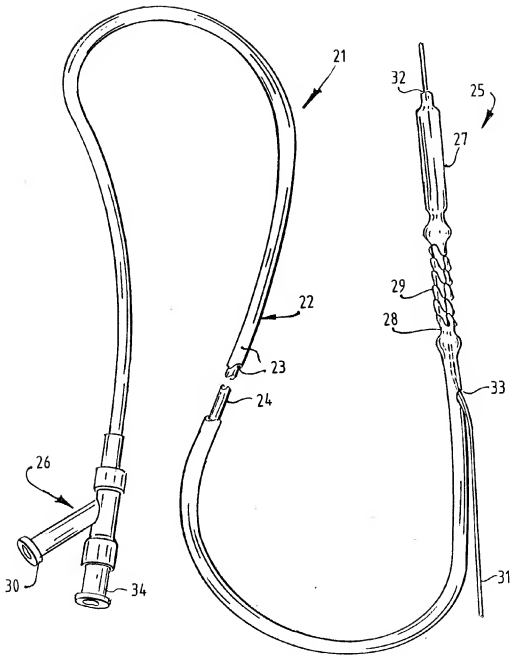

FIG.7

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 20 2790

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 442 657 (BARD) 21 August 1991 * column 7, line 24 - column 8, line 53; figures *	1-3	A61F2/06 A61M25/10
Y	EP-A-0 274 846 (ADVANCED SURGICAL INTERVENTION) 20 July 1988 * column 7, line 44 - column 8, line 33; figures 2,20 *	1-3	
Y	EP-A-0 528 039 (IGAKI) 24 February 1993 * column 5, line 20 - column 6, line 5; figure 4 *	1-3	
D,A	US-A-5 226 889 (SHEIBAN) 13 July 1993 * the whole document *	1,4-6	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	2 February 1996	Kousouretas, I

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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(71) Applicants:
- **CORDIS EUROPA N.V.**
  NL-9301 LJ Roden (NL)
- **Sheiban, Imad**
  I-37126 Verona (IT)

(72) Inventors:
- **Sheiban, Imad**
  I-37126 Verona (IT)
- **Nap, Cornelis Philipus**
  NL-9345 AC Zevenhuizen (NL)

(74) Representative: **'t Jong, Bastiaan Jacobus**
Arnold & Siedsma,
Advocaten en Octrooigemachtigden,
Sweelinckplein 1
NL-2517 GK Den Haag (NL)

(54) Catheter for stent implantation

(57) The invention relates to a catheter comprising a tube-like basic body with a proximal and a distal end, at least one balloon member arranged close to the distal end. This balloon member is connected via a lumen in the basic body to a connecting member at the proximal end. Close to either end of the balloon member a bulge has been arranged to the basic body and wherein a compressed stent has been arranged around the balloon member and in between the bulges. The bulges have been arranged inside the balloon-shaped member.

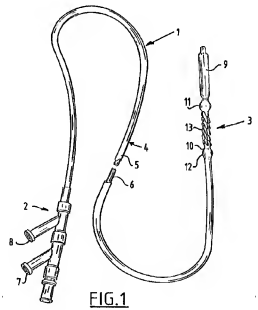

FIG.1

EP 0 707 837 A1

Description

The invention relates to a catheter used for the implantion of a stent in a patient. A stent is a tubular element, usually made of wire mesh, which can be expanded in cross-sectional direction. Such an element is for instance introduced into a blood vessel of a patient, of which the wall has been impaired to such a degree, that there is a risk of collapse of the blood vessel concerned. The stent is introduced in a compressed state and expanded when situated in the required position, thus supporting the wall of the blood vessel. Expansion is usually achieved by means of the balloon of a balloon catheter. Stents and catheters employed for the introduction thereof are known as such, and are for instance described in the American patent specification 5 226 889.

The object of this invention is to provide an improvement of known catheters used for the purpose of stent-implantation.

This aim has been achieved with the catheter according to the invention as characterised in claim 1. By employing the bulges in between which the stent is retained, the stent can be fixed securely at the site of the balloon used for expanding the stent. The stent cannot slide off the balloon. Because of this proper fixation of the stent, the use of a so-called sheath is superfluous, thus simplifying the treatment to be carried out using the catheter according to the invention. The bulges can consequently be arranged relatively close to each other, without limiting the expansion possibilities of the balloon. Consequently the stent can be fixed properly in the centre of the balloon. In the non-expanded state, the balloon fits closely over the bulges, so that the surface of the catheter in a longitudinal direction over the bulges is smooth.

For a good fixation of the stent it is sufficient if, in relation to the inside diameter of the compressed stent, the bulges are such that the stent cannot slide over these bulges. Preferably however the measure as characterised in claim 2 is employed. Consequently the stent is, as it were, situated in a depression or "bed" defined by the bulges, as a result of which the stent does not interfere with the introduction of the catheter.

A suitable embodiment is characterised in claim 3. The measure as set out in claim 4 is preferably employed. Both rings and therefore the position of the stent retained in between them, is in this way properly observable so that the stent can be manoeuvred carefully into the correct position.

Preferably the measure as set out in claim 5 is employed. The relatively distal balloon member can be used for dilatation of that section of the blood vessel where the stent is to be implanted, even when there is a severe stenosis. After dilatation of the blood vessel with the relatively distal balloon, the catheter is advanced a little further, thus positioning the stent in the dilated section of the blood vessel. Next the balloon around which the stent has been arranged can be expanded, as a result of which the stent will expand and provide the wall of the vessel with the required support. Thus, using one single catheter, and in one session, the vessel can be dilated and the stent implanted.

A suitable embodiment is characterised in claim 6.

The invention will be explained in greater detail in the following description with reference to the attached drawings.

Figure 1 shows a partly broken away, perspective view of a catheter according to the invention.

Figure 2 shows a partly cut away view of the distal end of the catheter of figure 1.

Figure 3 shows the catheter section shown in figure 1 during a first step of the treatment for which it is to be used.

Figure 4 shows a view corresponding to figure 3 of a second step of the treatment.

Figure 5 shows a view corresponding to figure 3 and 4 of a third step of the treatment.

Figure 6 shows schematically the treated blood vessel with the stent in position, following the removal of the catheter.

Figure 7 shows a partly broken away, perspective view of a catheter according to another embodiment of the invention.

The catheter 1 shown in figure 1 comprises a tube-like basic body 4 which in this case is made up of an outer tube-like element 5 and an inner tube-like element 6 received inside a lumen thereof. The inner tub-like element 6 has two lumens 16, 17. With the embodiment shown, two balloon members 9, 10 have been arranged at the distal end 3 of the catheter 1. At the proximal end 2 two connecting members 7, 8 have been arranged which are connected to the balloon member 9 and the balloon member 10 respectively. By supplying medium under pressure via the connectors 7 or 8, the balloon members 9 or 10 can be expanded. The connection between the connecting member 7 and the balloon member 9 runs via lumen 17 of the inner tube-like element 6 and the connection between the connecting member 8 and the balloon member 10 runs via the interspace 20 in between the inner tube-like element 6 and the outer tube-like element 5. Lumen 16 is intended for receiving a guide wire.

On both sides of the balloon member 10, the catheter 1 has been provided with bulges 11, 12. A compressed stent 13 has been arranged around the balloon 10 in between those bulges 11 and 12. The stent 13 is enclosed by the bulges 11 and 12 in the axial direction of the catheter 1, so that it cannot slide off the balloon 10.

As can be seen in figure 2 et seq. in particular, the bulges 11 and 12 in this embodiment are formed by respective rings 14 and 15 which have been received inside the balloon 10. The ring 14 has been arranged around the continuous inner tube-like element 6 and the ring 15 has been arranged around the end of the outer

tube-like element 5. As the rings 14, 15 have been arranged inside the balloon 10 they do not interfere with the unfolding of the balloon 10, and the balloon forms a smooth "skin" over the rings 14, 15, which is favourable when introducing the catheter.

The distal end 3 of the catheter 1 is introduced into a blood vessel 18 of a patient inside of which the stent 13 is to be implanted. The embodiment of the catheter according to the invention shown here is provided with the balloon 9 for dilating a narrowed blood vessel 18, in addition to the balloon 10 designed for expanding the stent 13. By employing the two balloons 9, 10, dilating the vessel and implanting the stent can be achieved using one and the same catheter 1, without it being necessary to change catheters.

With the treatment the catheter 1 is first introduced into the blood vessel 18 to such a degree that the first balloon 9 is positioned at the stenosed section which is to be dilated. Subsequently a medium under pressure is supplied via the connecting member 7 through the lumen 17 of the inner tube-like element 6. Via the opening 21 in the wall of the inner tube-like member this medium under pressure flows into the balloon 9 as a result of which it will expand. Consequently the blood vessel 18 will be dilated (fig. 3).

Next the pressure inside the balloon 9 will be reduced, as a result of which it will resume its original shape. The catheter is advanced further into the vessel so that the balloon 10 will be situated at the dilated section of the vessel. By supplying medium under pressure to balloon 10 via connector 8 and the interspace between the tube-like elements 5, 6, which interspace is connected with the inside of the balloon 10 at the end of the outer tube-like element 5 as a ring-shaped opening 20, this balloon 10, and hence the stent 13, will be expanded. This situation has been illustrated in figure 4.

Subsequently one allows the pressure in the balloon 10 to fall, as a result of which the balloon 10 will resume its original shape with small diameter as shown in figure 5. The catheter can now be withdrawn, whereby as is shown in figure 6, the stent 13 remains behind in the blood vessel 18, in order to support the wall thereof.

The catheter and the accompanying stent shown in the figures only represent examples of embodiments. Other embodiments of stents known as such, can be used in conjunction with the catheter according to the invention. Because of the good axial fixation of the stent, the latter will remain positioned in a reliable manner at the site of the balloon used for the purpose of expansion, so that it is not necessary to use a guiding catheter or a sheath.

The catheter according to the invention may comprise any number of balloon-shaped members, of which at least one comprises bulges on either side to retain a stent.

In the embodiment shown, the rings 14 and 15 have been made of material which is clearly visible when subjected to X-rays, so that the position of these rings 14, 15 and consequently the position of the stent, placed in between these bulges, can be rendered clearly visible in a catheterization laboratory.

The catheter 21 shown in figure 7 corresponds for the major part with the catheter 1 of figure 1. This catheter 21 thus comprises a tube-like basic body 22 with a distal end 25 and a proximal end 26. At the distal end 25 two balloons 27, 28 have been arranged. The balloon 27 is for dilating a narrowed section of a blood vessel. Around the balloon 28, a stent 29 has been arranged in compressed state. This stent 29 can be expanded, as described before, by means of the balloon 28 and thus be implanted in the section of the vessel dilated beforehand by means of the balloon 27.

With the embodiment shown, the basic body 22 is made up of an outer tube-like element 23 and an inner tube-like element 24. A lumen inside the inner tube-like element 24 has at the proximal end of the catheter 21 been connected to a connection 34, and at the distal end to the inside of the balloon 27 in order to convey medium under pressure from the connection 34 to the balloon 27 in order to expand the latter. In between the inner tube-like element 24 and the outer tube-like element 23, a in cross-section circular lumen is formed which, at the proximal end 26 of the catheter, is connected to the connection 30 and at the distal end 25 to the inside of the balloon 28 in order to be able to expand the latter in a similar manner.

For introducing the catheter into a patient a guide wire 31 is employed in the usual manner. For the purpose of receiving this guide wire 31 a lumen 36 has been formed in the catheter 21 which extends from an end hole 32 to a wall hole 33 in the catheter. This wall hole has been arranged in the wall of the basic body 22 at a position in between the distal and the proximal end.

With the preferred embodiment shown in figure 7, the wall hole has been arranged close to the relatively proximal active element of the catheter 21, the balloon 28. The lumen 36 for receiving the guide wire 31 only extends therefore through the end-section of the catheter 21.

Claims

1. Catheter comprising a tube-like basic body with a proximal and a distal end, at least one balloon member arranged close to the distal end which is connected via a lumen in the basic body to a connecting member at the proximal end, wherein close to either end of the balloon member a bulge has been arranged to the basic body and wherein a compressed stent has been arranged around the balloon member and in between the bulges, and wherein the bulges have been arranged inside the balloon-shaped member.

2. Catheter as claimed in claim 1, wherein the outside diameter of the compressed stent is smaller than the outside diameter of the catheter at the site of the bulges.

3. Catheter as claimed in one of the previous claims, wherein the bulges are formed by rings arranged around the basic body.

4. Catheter as claimed in claim 3, wherein each ring has been made of material visible when subjected to X-rays and/or when used in conjunction with an NMR device.

5. Catheter as claimed in one of the previous claims, comprising two successive balloon members, wherein the bulges and the stent are arranged at the site of the relatively proximal balloon member.

6. Catheter as claimed in claim 5, wherein the basic body comprises an outer tube-like element with a lumen inside of which an inner tube-like element has been received, a lumen of the inner tube-like element has been connected with the relatively distal balloon member and the interspace between the inner tube-like member and the outer tube-like member is connected with the comparatively proximal balloon-shaped member.

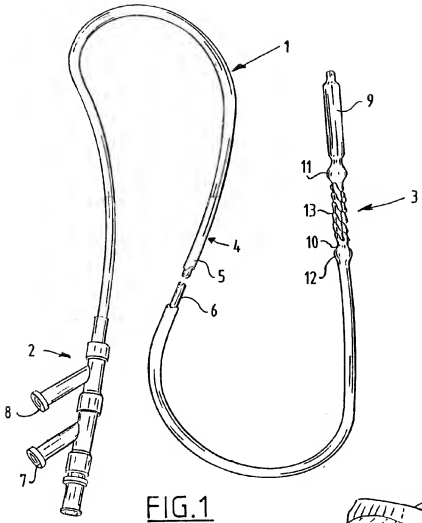

FIG.1

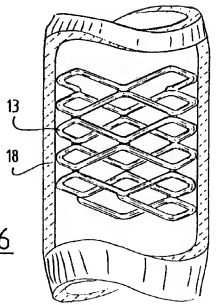

FIG.6

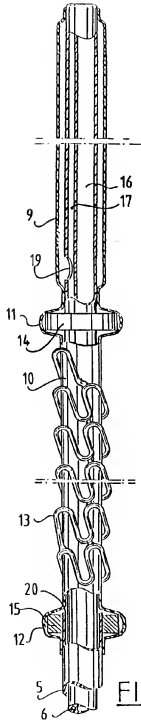

FIG.2

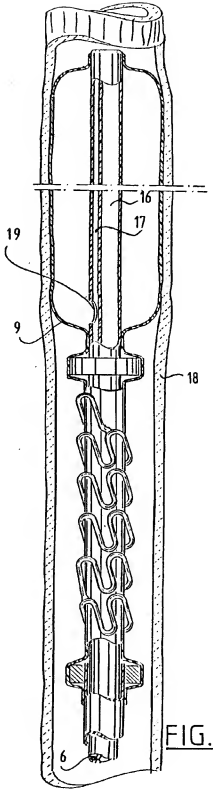

FIG.3

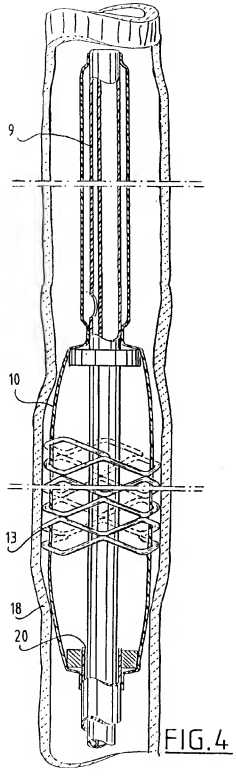

FIG.4

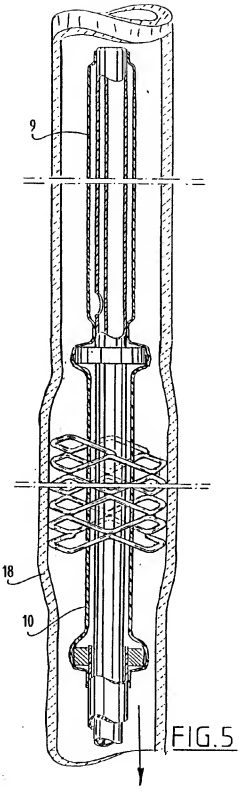

FIG.5

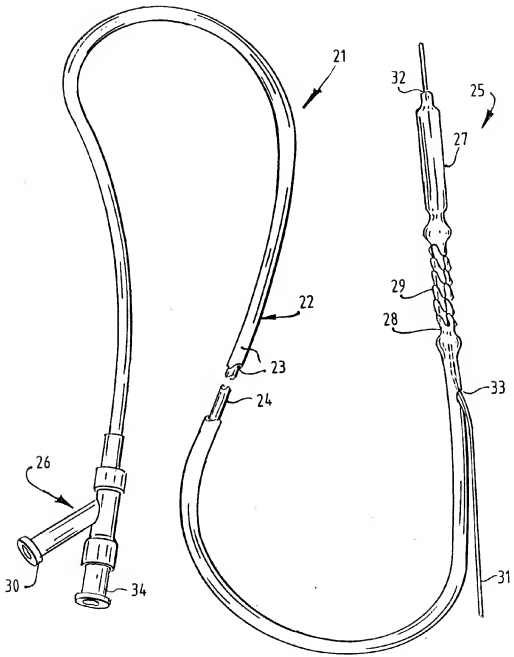

FIG.7

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EUROPEAN SEARCH REPORT

Application Number
EP 95 20 2790

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 442 657 (BARD) 21 August 1991 * column 7, line 24 - column 8, line 53; figures *	1-3	A61F2/06 A61M25/10
Y	EP-A-0 274 846 (ADVANCED SURGICAL INTERVENTION) 20 July 1988 * column 7, line 44 - column 8, line 33; figures 2,20 *	1-3	
Y	EP-A-0 528 039 (IGAKI) 24 February 1993 * column 5, line 20 - column 6, line 5; figure 4 *	1-3	
D,A	US-A-5 226 889 (SHEIBAN) 13 July 1993 * the whole document *	1,4-6	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61F
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	2 February 1996	Kousouretas, I

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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